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PTO/SB/21 (03-03)  
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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/626,943	
	Filing Date	July 25, 2003	
	First Named Inventor	Rubino et al	
	Group Art Unit		
	Examiner Name		
Total Number of Pages in this Submission	5	Attorney Docket Number	AM-100802USA

**ENCLOSURES (check all that apply)**

<input checked="" type="checkbox"/> Fee Transmittal Form <input checked="" type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): 12-References 10 pp. Search Report
Remarks		

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm or Individual Name	HOWSON AND HOWSON Cathy A. Kodroff
Signature	<i>Cathy A. Kodroff</i>
Date	November 21, 2003

**CERTIFICATE OF TRANSMISSION/MAILING**

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on this date:			
Typed or printed name			
Signature		Date	

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450

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The PTO did not receive the following listed item(s) Fee Transmittal  
& Fee



AM-100802USA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of	) Group Art Unit:
	)
Rubino et al	) Examiner:
	)
Appln. No. 10/626,943	)
	)
Filed: July 25, 2003	)
	)
For: PARENTERAL FORMULATIONS	) November 21, 2003

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

Applicant submits to the Examiner the attached Form PTO/SB/08A document listing and this paper pursuant to 37 CFR § 1.56 and § 1.97-1.98. Form PTO/SB/08A is attached and a copy of the documents are enclosed herewith.

Each item of information contained in this Information Disclosure Statement (IDS) was first cited in communication from a foreign patent office in a related international application less than three months prior to the filing of this IDS. Therefore, no fee is due.

The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper or credit any overpayment in any fees to our Deposit Account Number 08-3040.

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## REMARKS

Listed are documents cited in the International Search Report dated November 6, 2003 in the corresponding International Patent Application No. PCT/US03/23276. A copy of the Report is enclosed, together with copies of the documents listed therein.

Item [MM] is in German, and corresponds to US patent 6,565,859, item [HH]. This document relates to an oral composition comprising a rapamycin compound.

A translation is provided in item [HH].

The Examiner is respectfully requested to consider the enclosed documents identified in this paper and in the attached Form PTO/SB/08A during the course of examination of this application.

Respectfully submitted,

HOWSON AND HOWSON  
Attorneys for Applicant

By



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PTO/SB/08A (08-00)  
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<b>Substitute for form 1449/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/626,943
				Filing Date	July 25, 2003
				First Named Inventor	Rubino et al
				Group Art Unit	
				Examiner Name	
Sheet	1	of	1	Attorney Docket Number	AM-100802USA

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	CC	US 5516770	05-14-1996	Waranis et al	
	DD	US 5530006	06-25-1996	Enever et al	
	EE	US 5536729	07-16-1996	Leonard et al	
	FF	US 5559121	09-24-1996	Harrison et al	
	GG	US 5616588	04-01-1997	Waranis et al	
	HH	US 6565859	05-20-2003	Fricker et al	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)						
	II ✓	EP	0649659	A1	04-26-1995	American Home Products		
	JJ ✓	EP	0650730	A1	05-03-1995	American Home Products		
	KK ✓	PCT	01 97809	A2	12-27-2001	American Home Products		
	LL ✓	EP	0041795	A2	12-16-1981	Ayerst et al		
	MM ✓	DE	4418115	A1	12-01-1994	Sandoz		
	NN ✓	GB	2327611	A	02-03-1999	Novartis		

Examiner Signature		Date Considered	
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\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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